

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**DEFENDANTS' OBJECTIONS TO THE MEMORANDUM ORDER
DENYING DEFENDANTS' MOTION TO COMPEL
AND MOTION FOR BILL OF PARTICULARS**

Pursuant to Federal Rule of Criminal Procedure 59(a), Indivior Inc. and Indivior PLC (collectively, "Indivior") respectfully object to Magistrate Judge Sargent's October 16, 2019 Memorandum Order denying Indivior's Motion to Compel and Motion for Bill of Particulars (ECF No. 220) (hereinafter, "Order"). On the substance of both Motions, Magistrate Judge Sargent's Order is both contrary to law and clearly erroneous, and is thus subject to mandatory modification by this Court. *See* Fed. R. Crim. P. 59(a). Accordingly, Indivior respectfully requests that this Court vacate the Order, grant Indivior's Motion to Compel seeking the government's full compliance with its *Brady* and Rule 16 obligations (*see* ECF Nos. 117, 118, and 175), and order that the government produce a bill of particulars so that Indivior may adequately prepare a defense and avoid unfair surprise at trial (*see* ECF Nos. 136, 137, and 185).

STANDARD OF REVIEW

Under the standard set forth in Rule 59(a), when a party files objections to a magistrate judge's order on a non-dispositive matter, this Court must consider the objections and "modify or set aside any part of the order that is contrary to law or clearly erroneous." Fed. R. Crim. P.

59(a). An order is contrary to law “when it fails to apply or misapplies relevant statutes, case law, or rules of procedure.” *United States v. Dunlap*, No. 1:12CR00044-044, 2013 WL 30145, at *1 (W.D. Va. Jan. 2, 2013) (internal quotation marks omitted). And an order is clearly erroneous when “although there is evidence to support it,” the reviewing court, after considering all the evidence, “is left with the definite and firm conviction that a mistake has been committed.” *Minyard Enterprises, Inc. v. Se. Chem. & Solvent Co.*, 184 F.3d 373, 380 (4th Cir. 1999) (internal quotation marks omitted).

ARGUMENT

I. Motion to Compel

The portion of Magistrate Judge Sargent’s Order addressing Indivior’s Motion to Compel is contrary to the Supreme Court’s clear directive in *Kyles v. Whitley* that the prosecution must disclose any evidence favorable to the defense that is *known* either to the prosecution or “*known* to the others acting on the government’s behalf in the case.” 514 U.S. 419, 437-38 (1995) (emphasis added). Although the Order refers to this controlling standard, it does not actually address the favorable evidence within the possession of certain key federal agencies that is known to the prosecution team but that has not yet been produced to Indivior. *See* Mem. in Support of Def. Mot. to Compel at 8-18 (ECF No. 118); Reply in Support of Def. Mot. to Compel at 4-12 (ECF No. 175). Instead, the Order focuses narrowly on the agencies that participated in the investigation and states that Indivior is seeking an order requiring the government to “gather and disclose information from various branches of HHS and other law enforcement agencies of the Department of Justice, which the Government has stated were not involved in the investigation and are not involved in this prosecution.” Order at 9. Magistrate Judge Sargent’s apparent conclusion is that Indivior is not entitled to such information because the agency “branches” in actual possession of these materials are not within the government’s

definition of the investigative team. *See id.* But this conclusion does not address whether members of the prosecution team nevertheless *know* about the material and favorable information Indivior has identified, thus bringing that information within the scope of what the government is required to produce under *Kyles*, regardless of who possesses it.

At no point has the government denied knowledge of the agency information Indivior has identified as being material to the preparation of its defense and, in some cases, exculpatory. Nor could it. Indivior has in its briefs filed in support of its Motion to Compel explicitly addressed the categories of information in the possession of these agencies that the government must produce. For example:

- Indivior has identified as material to its defense the analysis on unit-dose packaging from the Centers for Disease Control and Prevention (“CDC”), an operating division of the Department of Health and Human Services, which was one of the agencies on the investigative team in this case. In 2016, multiple CDC employees, together with others from the Food and Drug Administration (“FDA”), published findings from a study regarding the rates of pediatric emergency room visits for buprenorphine/naloxone ingestions, which dropped by two thirds when prescriptions dispensed in unit-dose packaging increased to over 80%.¹ Rather than speaking to and collecting documents from all the CDC employees who reached this conclusion, which is exculpatory as to the purported falsity of Indivior’s alleged representations on the safety of Suboxone film versus Suboxone tablets, the government interviewed and obtained documents from just one. *See Reply in Support of Def. Mot. to Compel* at 10. Moreover, the government has

¹ Daniel S. Budnitz, et al., Centers for Disease Control and Prevention, Notes from the Field: Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion—United States, 2008-2015, 65 Morbidity & Mortality Wkly. Rep. 1148 (2016).

failed to produce the additional material in the possession of the CDC, reflecting the CDC's analysis of the impact of unit-dose packaging on pediatric exposure, that is referenced in the government's *own memorandum* of its interview with that one CDC employee. *See id.* at 10-11.

- Indivior has also identified as material to its defense the documents and other information underlying the conclusions reached by four FDA divisions and offices in 2012 and 2013 that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging," as well as the FDA's recommendation to generic buprenorphine manufacturers in April 2013 that they voluntarily switch to unit-dose packaging for their buprenorphine-containing products. *See* Mem. in Support of Def. Mot. to Compel at 17; Reply in Support of Def. Mot. to Compel at 7. Although the government has produced to Indivior a single file from the FDA's Center for Drug Evaluation and Research with documents tied to the FDA's consideration of the Citizen Petition submitted by Indivior (then known as Reckitt Benckiser Pharmaceuticals, Inc.), the government has refused to obtain from the FDA the additional material tied to its consideration of the pediatric exposure issue and its guidance to generic manufactures. The government clearly knows about the FDA's conclusions and related recommendation on this issue, and has charged Indivior with making *false* statements regarding the comparative safety of Suboxone film and Suboxone tablets, making any claim that the information is not within the government's Rule 16 and *Brady* obligations to produce untenable.
- In addition, Indivior has pointed to the Drug Enforcement Administration ("DEA") files for each of the doctors it is apparently accused of aiding and abetting to issue

prescriptions in a “careless and clinically unwarranted manner” as another example of information material to its defense. *See* Indictment ¶ 31 (ECF No. 3). Although any action, or inaction, on the part of the DEA as to these physicians will be critical evidence reflecting the government’s own view of the propriety of the physicians’ prescribing practices and any need to intervene, the government has refused to produce the information. Whether the DEA actually ever investigated these physicians—and/or received information from the pharmacies that filled prescriptions written by the physicians—is not dispositive on the question of materiality: if it did, and there was no finding or action taken, that information will show that the agency charged with monitoring such activities did not view the physicians’ prescribing practices to be actionable; and if it did not, that too shows a lack of concern regarding the physicians’ methods of prescribing. Either answer is material to Indivior’s preparation of its defense and is exculpatory evidence to which it is entitled.

Instead of collecting and producing these and other specified materials, the government has instead argued that it has complied with its *Brady* and Rule 16 obligations by collecting a limited subset of materials from these key government agencies and producing them to Indivior. *See* Gov. Response in Opposition to Indivior’s Mot. to Compel at 9-13 (ECF No. 146) (identifying select materials produced to Indivior from the DEA, FDA, CDC, and Substance Abuse and Mental Health Services Administration). But picking and choosing which favorable evidence to collect and subsequently produce to the defense is inconsistent with *Kyles*, which requires the production of all favorable evidence known to any member of the prosecution team. *See Kyles*, 514 U.S. at 437-38. If the government has obtained *some* information or evidence from an agency, it cannot shirk its responsibility to obtain *all* information or evidence in the

possession of that agency that would be material to the defense. *See, e.g., United States v. Cerna*, 633 F. Supp. 2d 1053, 1060 (N.D. Cal. 2009) (when the prosecution is making written or verbal requests for records, it must be “even-handed as to the point of inquiry,” meaning that the “prosecutor must ask for *all* information on the same subject, pro and con”); *United States v. W.R. Grace*, 401 F. Supp. 2d 1069, 1079 (D. Mont. 2005) (“The prosecution may not simply ask for information it wants while leaving behind other, potentially exculpatory information within agency files.”). Nor can it bury its head in the sand and refuse to ask other members of the investigative team about any other known information that would be favorable to Indivior’s defense. *See Carriger v. Stewart*, 132 F.3d 463, 480 (9th Cir. 1997) (“Because the prosecution is in a unique position to obtain information known to other agents of the government, it may not be excused from disclosing what it does not know but could have learned.” (citing *Kyles*, 514 U.S. at 438-40)).

In overlooking Indivior’s clearly identified categories of favorable and exculpatory material that has not yet been produced, Magistrate Judge Sargent’s Order cites the Fourth Circuit’s opinion in *Fullwood v. Lee*, 290 F.3d 663 (4th Cir. 2002), and states that “*Brady* does not require the Government to disclose evidence, even if it is exculpatory, already known by the defense.” Order at 9. But the *Fullwood* decision does not address simple knowledge on the part of the defense that there is material evidence that has not yet been produced. 290 F.3d at 686. Instead, *Fullwood* explains that *Brady* does not compel disclosure “of evidence available to the defendant from other sources” or require the government to disclose a particular fact that is already known to the defense (e.g., in *Fullwood*, the defendant’s own knowledge of his cocaine usage on the night of the relevant murder). *Id.* (internal quotation marks omitted). Awareness that material evidence exists is, of course, different from access to the evidence. While Indivior

can point to the categories of information in the possession of the key federal agencies that are material to the preparation of its defense and/or exculpatory, it is the government that has access to these government materials, as it has demonstrated already in this case. Indivior cannot simply request the information and reasonably expect to receive it in time to meaningfully prepare for and “make effective use of [the information] at trial.” *See United States v. Shifflett*, 798 F. Supp. 354, 357 (W.D. Va. 1992) (addressing the manner in which *Brady* and its progeny require that exculpatory material be disclosed). Moreover, while Indivior is able to discern, through its review of publicly available information and the select materials produced by the government, that the government’s production is incomplete, it does not know all the specific facts contained within the missing materials. Without this information, Indivior will be severely hampered, if not derailed completely, in its effort to identify agency documents as trial exhibits and, more importantly, potential trial witnesses employed by the government.

Rather than taking an agency-by-agency approach to address the missing information identified by Indivior, Magistrate Judge Sargent focused narrowly on the agency divisions identified by the government as having participated in the investigation, and accepted the government’s representation that there is no further Rule 16 or *Brady* material to produce. The failure to consider the other categories of information identified by Indivior is clearly erroneous, and the apparent wholesale rejection of Indivior’s argument that the government must produce these materials because they are known to the investigative team is contrary to the Supreme Court’s clear directive in *Kyles*. For these reasons, and for the reasons addressed in Indivior’s Memorandum in Support of Defendants’ Motion to Compel (ECF No. 118) and Reply in Support of Defendants’ Motion to Compel (ECF No. 175), Indivior respectfully requests that the Court vacate Magistrate Judge Sargent’s Order and grant Indivior’s Motion to Compel.

II. Motion for Bill of Particulars

Indivior further objects to Magistrate Judge Sargent's Order insofar as it includes a wholesale denial of its Motion for Bill of Particulars without addressing many of the key particulars lacking in the Indictment that courts routinely order the government to provide to allow defendants to effectively prepare for trial. Magistrate Judge Sargent's statement that all of Indivior's specific requests that were not addressed in the Order "amount to nothing more than an effort to be provided with the Government's evidence in advance of trial," Order at 6, is simply inaccurate. And the failure to consider Indivior's need for this specific information to prepare for trial and prevent undue surprise is clearly erroneous. As it stands, the Order will require Indivior to "waste precious pre-trial preparation time guessing" about the nature of the government's charges even though the government knows precisely the nature of the charges it is asserting and "can easily provide the information." *United States v. Trie*, 21 F. Supp. 2d 7, 21 (D.D.C. 1998).

For example, both the court and the government failed even to address Indivior's request that the government disclose the identity of Indivior's purported co-conspirators. Although the Indictment alleges that between 2006 and 2019, Indivior conspired with "others known and unknown to the Grand Jury" to commit mail fraud, wire fraud, and health care fraud, the Indictment does not identify a single co-conspirator. Indictment at p. 36-37. As Indivior explained in its briefs supporting its Motion for Bill of Particulars, courts have routinely ordered bills of particulars requiring the government to disclose the names of co-conspirators. *See, e.g., United States v. Am. Waste Fibers Co.*, 809 F.2d 1044, 1047 (4th Cir. 1987) (proper remedy for indictment that omits names of co-conspirators is to seek a bill of particulars); *United States v. Coleman*, No. 3:17-CR-00008, 2018 WL 1386265, at *5 (W.D. Va. Mar. 19, 2018) (directing the government to disclose in a bill of particulars "the names of the co-conspirators the Government

may use as witnesses”); *United States v. Allen*, 289 F. Supp. 2d 230, 238 (N.D.N.Y. 2003) (directing government to disclose “the identities of all persons the government claims to have been co-conspirators during the course of the alleged conspiracy, regardless of whether they have been indicted”); *United States v. Holman*, 490 F. Supp. 755, 762 (E.D. Pa. 1980) (similar). Neither the government nor Magistrate Judge Sargent provided any justification for why the government need not do so in this case.² Without disclosure of the purported co-conspirators, Indivior cannot meaningfully prepare a defense because it can only guess as to who the government may reference at trial as having participated in the alleged conspiracy.

Similarly, Magistrate Judge Sargent did not address Indivior’s request that the government disclose each of the false or fraudulent statements it intends to introduce at trial and the factual basis for the alleged falsity or fraudulence. While the Order points to select purportedly false statements in the Indictment, it ignores the Indictment’s apparent disclaimer that the allegations included are merely “illustrative examples,” rather than “an exhaustive list” of all the purportedly false and fraudulent statements the government apparently intends to introduce at trial. Indictment ¶¶ 42 n.2, 102 n.5. In addition, the Indictment alleges a conspiracy and fraudulent conduct that lasted from 2006 through the date of the Indictment in 2019, Indictment ¶¶ 31-32, 78, but does not identify a single allegedly false or fraudulent statement or representation made after 2016. Indivior has simply requested that the government particularize *every* purportedly fraudulent statement it seeks to introduce at trial and the basis for its alleged fraudulence. Courts have routinely ordered the government to provide this information so that a

² At the hearing on Indivior’s Motion to Compel, Magistrate Judge Sargent asked the government, “shouldn’t they have a right to know who the co-conspirators are?” Transcript of Oct. 1, 2019 Hearing at 29 (ECF No. 205). The government did not respond to the question directly, instead suggesting that they had disclosed the individuals involved in the purported conspiracy, explaining that there are “a lot” of them. *Id.* But the government did not disclose any information about the co-conspirators in the Indictment, and Magistrate Judge Sargent did not address this issue in the Order.

defendant can adequately prepare for trial. *See, e.g., United States v. Magalnik*, 160 F. Supp. 3d 909, 918 (W.D. Va. 2015) (ordering government to list “the specific visa and/or work applications that it intends to introduce at trial and explain, in general terms, how each application is believed to be false or fraudulent”); *United States v. Elbaz*, 332 F. Supp. 3d 960, 982-83 (D. Md. 2018) (ordering government to list all allegedly false statements “that it intends to introduce at trial, including the date of the statement and the person to whom it was made”); *United States v. Anderson*, 441 F. Supp. 2d 15, 20 (D.D.C. 2006) (holding that the defendant is “entitled to know precisely which allegedly false statements the government relies on in each paragraph, the way in which the government alleges them to be false, and when approximately they were allegedly made”).

In addition, Magistrate Judge Sargent’s Order has done nothing to clarify for Indivior the nature and particulars of the government’s apparent claim that, through its marketing, Indivior somehow aided and abetted physicians in prescribing and dispensing Suboxone Film in a “careless and clinically unwarranted manner.” *See* Indictment ¶ 31, p. 26. The allegation suggests that Indivior somehow intentionally aided and abetted *careless* conduct on the part of physicians, and that the government believes such *careless* conduct by these physicians gives rise to federal criminal *fraud* charges. But the Indictment does not define what it deems to be “careless and clinically unwarranted” prescribing or dispensing, address how Indivior’s marketing aided physicians in prescribing or dispensing Suboxone Film in a “careless and clinically unwarranted” manner, or link any false or fraudulent statements to the purported “careless and clinically unwarranted” prescribing practices.

During the hearing on Indivior’s Motion for Bill of Particulars, even the government seemed confused about what it was actually charging in the Indictment. When Magistrate Judge

Sargent asked the government about the portion of the Indictment suggesting that Indivior somehow, through its marketing, aided and abetted health care providers in prescribing and dispensing Suboxone film in a careless and clinically unwarranted manner, Mr. Ramseyer explained that the scheme alleged in the Indictment is “to switch doctors from pills to film.” Transcript of Oct. 1, 2019 Hearing at 33-34. When Magistrate Judge Sargent clarified that the “government’s case is not that . . . the defendants were urging these doctors to prescribe film to more patients, or to prescribe [more] than they should legally be handling, or to prescribe it in doses higher than was shown to be clinically effective,” Mr. Ramseyer responded, “[w]e would agree we wouldn’t be required to prove that.” *Id.* at 36. But at the end of the hearing, Mr. Mayer suggested that the alleged scheme is something slightly different—that is, knowingly referring patients to doctors who were “issuing prescriptions that are careless and clinically unwarranted,” and getting those doctors to prescribe Suboxone Film. *Id.* at 45. Mr. Mayer stated, “that’s part of the conspiracy and that’s part of the fraud.” *Id.*

But the Indictment itself suggests an even different scheme, whereby Indivior was “marketing Suboxone film to health care providers *to be prescribed and dispensed* in a careless and clinically unwarranted manner.” Indictment at 26 (emphasis added). Although Magistrate Judge Sargent’s Order points to paragraphs listing conduct the government alleges “induced or procured the physicians *to switch to prescribing Suboxone Film*,” Order at 5 (emphasis added), it does not identify anything in the Indictment supporting a claim that Indivior somehow aided and abetted the physicians’ prescribing practices. On the one hand, the government is apparently asserting that the physicians are the victims of Indivior’s scheme, and on the other, it is apparently claiming the physicians are Indivior’s co-conspirators. Given that the government has not submitted any filing clarifying this issue, and Magistrate Judge Sargent has not ordered

the government to do so, Indivior will remain in the dark about whether and how the government intends to proceed on this undefined claim, inhibiting its preparation for trial and leaving the door open to undue surprise.

Indivior is not asking the government to disclose all the evidence it plans to use at trial. It is simply requesting that the government fill the gaps in the Indictment and provide Indivior with the critical information it needs to adequately prepare a defense and avoid unfair surprise at trial. Magistrate Judge Sargent's wholesale denial of the Motion for Bill of Particulars without addressing these issues is both clearly erroneous and contrary to law. For these reasons, and for the reasons addressed in Indivior's Memorandum in Support of Defendants' Motion for Bill of Particulars (ECF No. 137) and Reply in Support of Defendants' Motion for Bill of Particulars (ECF No. 185), Indivior respectfully requests that the Court vacate Magistrate Judge Sargent's Order and grant Indivior's Motion for Bill of Particulars.

CONCLUSION

For the foregoing reasons, and for the reasons addressed in Indivior's opening and reply briefs supporting its motions, Indivior respectfully requests that the Court vacate Magistrate Judge Sargent's Order and grant its Motion to Compel and Motion for Bill Particulars. Indivior also requests a hearing before the Court to further address the foregoing objections.

Dated: October 30, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser
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/s/ Thomas J. Bondurant, Jr.

By Counsel

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 30th day of October, 2019.

/s/ Thomas J. Bondurant, Jr.

Counsel for Defendants